

**Statement of Work
Radiation Safety Program
VA Palo Alto Health Care System**

Section 1: General Information

1.1 General: This is a non-personal services contract to provide a radiation safety program for the VA Palo Alto Health Care System (VAPAHCS). The Government shall not exercise any supervision or control over the contract service providers performing the services herein. Such contract service providers shall be accountable solely to the Contractor who, in turn is responsible to the Government. The contractor shall perform to the standards in this contract.

1.2 Background: A Radiation Safety Program, overseen by a Radiation Safety Officer (RSO), must be in place for all sites licensed to use radioactive materials for medical use. This program ensures that all radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.

1.3 Period of Performance:

Base Year:	April 1, 2017 to March 31, 2018
Option Year #1:	April 1, 2018 to March 31, 2019
Option Year #2:	April 1, 2019 to March 31, 2020

1.4 Place of Performance: VA Palo Alto Health Care System
3801 Miranda Ave.
Palo Alto, CA 94304

1.5 Hours of Operation: The majority of the work under this Statement of Work will be between regular business hours of 7:00 A.M. to 6:00 P.M. Monday thru Friday except Federal holidays. Please note that the contractor is required to provide **24 hour support** for radiation emergencies such as spills, fires and other radiologic incidents. In addition the Federal holidays, the following days observed as official Stanford University holidays: The day after Thanksgiving and Christmas Eve.

1.6 Type of Contract: The government will award a Firm Fixed Price contract.

1.7 Invoicing: All invoices from the contractor shall be submitted electronically in accordance with VAAR Clause 852.232-72 Electronic Submission of Payment Requests.

VA's Electronic Invoice Presentment and Payment System – The FSC uses a third-party contractor, Tungsten, to transition vendors from paper to electronic invoice submission. Please go to this website: <http://www.tungsten-network.com/US/en/veterans-affairs/> to begin submitting electronic invoices, free of charge.

More information on the VA Financial Services Center is available at <http://www.fsc.va.gov/einvoice.asp>.

Vendor e-Invoice Set-Up Information:

Please contact Tungsten at the phone number or email address listed below to begin submitting your electronic invoices to the VA Financial Services Center for payment processing, free of charge. If you have question about the e-invoicing program or Tungsten, please contact the FSC at the phone number or email address listed below:

- Tungsten e-Invoice Setup Information: 1-877-489-6135
- Tungsten e-Invoice email: VA.Registration@Tungsten-Network.com
- FSC e-Invoice Contact Information: 1-877-353-9791
- FSC e-invoice email: vafscshd@va.gov

Section 2: Definitions & Acronyms

2.1 Definitions:

Contractor. A supplier or vendor awarded a contract to provide specific supplies or service to the government. The term used in this contract refers to the prime.

Subcontractor. One that enters into a contract with a prime contractor. The Government does not have privity of contract with the subcontractor.

Work Day. The number of hours per day the Contractor provides services in accordance with the contract.

Work Week. Monday through Friday, unless specified otherwise.

2.2 Acronyms:

ACOS	Associate Chiefs of Staff
CO	Contracting Officer
COR	Contracting Officer Representative
FDA	Food and Drug Administration
NCRP	National Council on Radiation Protection
NRC	Nuclear Regulatory Commission
PWS	Performance Work Statement
VA	Veterans Affairs
VHA	Veterans Health Administration
VAPAHCS	Veteran Affairs Palo Alto Health Care System

Section 3: Government Furnished Property, Equipment, and Services

None

Section 4: Contractor Furnished Items and Services

Personnel assigned by the Contractor to perform the services identified shall be appropriately licensed by a State, Territory or Commonwealth of the United States of America, District of Columbia or by a national licensing organization in their field. Qualifications of such personnel shall also be subject to review by VAPAHCS Chief of Staff or approval by the Director, VAPAHCS.

Section 5: Specific Tasks

5.1 Coordination with Stanford University

- 1) The VA Palo Alto Health Care System (VAPAHCS) requires seamless radiation safety services to employees that go back and forth between the two institutions (VAPAHCS and Stanford University).
- 2) Faculty, residents, clinicians and researchers often have dual appointments or utilize the resources of both locations to meet the goals of their clinical practice or research, which includes the following:
 - a) Perform and maintain radiation monitoring for workers that go back and forth between VAPAHCS and Stanford University.
 - b) Dosimeter Requirements
 - c) Specify personnel radiation monitoring dosimeter requirements
 - d) Review reports of personnel radiation doses
 - e) Investigate unusual exposures that may have occurred at VAPAHCS, Stanford University, or both.
 - f) Maintain required dosimeter reports.
 - g) Advise on corrective action to prevent unnecessary exposures.
 - h) Assemble and maintain exposure history and provide to employees upon request, as required by law.
 - i) Provide dosimetric calculations and risk-to-patient assessments for research physicians who plan to perform investigational procedures using radiopharmaceuticals.
 - j) Utilize and integrate Stanford's Research compliance office, and the institutional Review Board (IRB). Contractor must have access to these services.
 - k) Provide access to utilize Stanford's Radiological Drug Research Committee (RDRC).
 - l) Contractor must have the ability to assemble and coordinate a committee as required by VAPAHCS as a radioactive material licensee, to oversee radioactive materials for clinical and research use (both human and non-human).

5.2 Services required for Nuclear Medicine

- 1) Perform initial review of proposed usage of radioisotopes. Evaluate hazards, propose necessary safety measures and issue licenses to possess isotopes.
- 2) Perform on-site inspections of facilities and recommend changes or improvements which may be required for radiation safety purposes.
- 3) Inspect incoming radioisotope shipments for contamination, radiation levels and authorization to possess materials. Provide training for new employees and supervision of employees assigned to inspect radioisotope shipments for clinical application received directly at VAPAHCS.
- 4) Maintain centralized inventory record system for radioisotopes which have been received, used and disposed of by VAPAHCS.
- 5) Periodically monitor each laboratory room for contamination, external radiation and compliance with posting and labeling requirements.
- 6) Provide a copy of the proposed monitoring schedule to the Contracting Officer within thirty (30) days of award of contract.
- 7) At the frequency stipulated in the National Health Physics Program (NHPP) license, or VA permits issued under the Master License, review each radiation research project to assess new or unforeseen hazards to insure compliance with regulations and licenses. Amend hazards evaluations when new uses are proposed.
- 8) Copies of any new regulations and VA NHPP policies shall be provided to the appropriate Radiation Safety Committee at least 30 days before implementation.
- 9) Train VA employees and other appropriate persons at the VA as required in radiation protection as required and/or when any deficiencies occur. Such training shall include training prior to use of radioactive materials and periodic updates. Mini-courses on topics related to specific research projects may be provided to support training of ancillary personnel and nurses.
- 10) Develop, and update as needed, standard operating procedures and advise care-giving staff on radiation protection methods applicable to care of patients who have received radioactivity as part of treatment or diagnosis.
- 11) Review and approve radiation safety instructions and standard operating procedures for various VAPAHCS services (e.g., Environmental Management, Engineering, Acquisition and Materiel Management, Pathology, Environmental Safety, etc.) who may incidentally be involved with radioactive materials or patients containing radioactivity.
- 12) Respond to radiation emergencies such as spills, fires and other radiologic incidents on a 24-hour basis.

- 13) Review and approve radiation emergency procedures for admitting patients who have been involved in radiation incidents. Respond, advise, and assist medical personnel in the event of such an admission.
- 14) Advise and assist, if requested, Pathology Service in autopsy procedures on patient remains containing radioisotopes, including preparation of special documents for release of remains to mortuaries.
- 15) Perform routine thyroid radioassays for radioiodine users, urine radioassays, or radioassays for other radioisotopes as appropriate to assure compliance with legal limits on internal exposure. Investigate causes of unusually high uptake levels.
- 16) Calibrate laboratory radiation monitoring instruments annually or as according to manufacturer specifications and maintain a calibration log.
- 17) Provide technical assistance in radioactive sample analysis where specialized equipment is required.
- 18) Conduct site inspection tours with VA staff and staff from regulatory agencies. Follow up on any cited deficiencies to insure they have been corrected.
- 19) Prepare any required or requested reports (e.g., exposures, losses or releases of materials, etc.), obtain required signatures, and submit to the appropriate regulatory agency. Copy of report shall be forwarded to Chief, Nuclear Medicine Service.
- 20) Review facilities and notify appropriate VA managers of deficiencies in safety or compliance-related issues. Maintain required histories of usage for radioactive materials and incidents involving releases of materials in accordance with decommissioning requirements of the Nuclear Regulatory Commission (NRC) and/or NHPP.
- 21) Prepare applications for renewal and amendment to NHPP permits for execution by the Director, VAPAHCS.
- 22) Perform annual evaluations of airborne releases of radioactive materials as required by NRC regulation or NHPP permit.
- 23) Provide staff support for radiation safety committees and for FDA radioactive drug research committees.
- 24) Dosimeter Requirements
 - a) Specify personnel radiation monitoring dosimeter requirements
 - b) Review reports of personnel radiation doses
 - c) Investigate unusual exposures.
 - d) Maintain required dosimeter reports.
 - e) Advise on corrective action to prevent unnecessary exposures.

- f) Assemble and maintain exposure history and provide to employees upon request, as required by law.
- g) Provide dosimetric calculations and risk-to-patient assessments for research physicians who plan to perform investigational procedures using radiopharmaceuticals.

25) Disposal of radioactive waste.

- a) Provide on-site pick-up, packaging, transportation and disposal of radioactive waste and containers from Nuclear Medicine Service and VAPAHCS research laboratories. This includes disposal of two 2-cubic foot containers and 4 sharps containers to be picked up each week for Nuclear Medicine, plus approximately 25 boxes per year from research groups not funded by Stanford University and for patients of Nuclear Medicine who are hospitalized.
- b) Waste pick-up shall be provided when requested.
- c) Packaging of radioactive waste by projects shall be in accordance with Stanford University, Environmental Health and Safety Department, Hazardous Waste Division, Radioactive Waste Section standards. Exceptions to these procedures will be in writing and will be approved by the Radioactive Waste Section supervisor.

26) Inventory and survey sealed radioactive sources at appropriate intervals per NRC regulations and VA NHPP requirements. Sealed source leakage will be documented as appropriate.

27) Provide advice, training, and oversight of the VAPAHCS Source of Concern per NRC regulations and NHPP permit conditions covering such sources.

28) Yttrium-90 Sirtex Sirspheres therapy for liver tumor radio embolization.

- a) Supervise the Y-90 Sirspheres dose draw from the Sirspheres vial utilizing NHPP approved protocol, and according to prescribed dose ordered by the authorized user on the written directive.
- b) Complete a survey of the preparation area, to ensure there is no radioactive contamination.
- c) Deliver the Y-90 vial with the prescribed dose to Interventional Radiology, and assist in any radioactive material and health physics needs that may arise during administration.
- d) Following administration, survey the Interventional Radiology room for radioactive contamination, and remove and dispose of all radioactive material and associated vials, syringes and tubes.

29) High dose Iodine-131 in-patient therapy for thyroid cancer

- a) Prepare hospital room for in-patient therapy, e.g., place absorbent, non-permeable barriers on floor and other areas that might be exposed with biological hazards.
- b) Train nurses and answer any questions or concerns they might have.
- c) Place appropriate regulatory signage in and around designated room
- d) Perform a daily room radiation survey and clean or remove any removable contamination.
- e) Release the room by surveying and, decontaminating if necessary, post patient-discharge.

5.2 Services required for Radiology Service

- 1) Contractor shall provide the routine services of the radiologic hazard survey program for all diagnostic radiographic imaging equipment located throughout VAPAHCS and its divisions.
- 2) Perform annual radiation protection survey inspections of all diagnostic radiographic imaging systems and as needed.
- 3) Inspections shall be directed to ascertain compliance with the National Council on Radiation Protection (NCRP), Joint Commission on Accreditation of Healthcare Organization (JCAHO) and Federal, certified equipment only, requirements or regulations.
- 4) A written report on the findings of each survey, including recommendations for any required corrective measures shall be issued. If further surveys are deemed necessary, it will be so indicated.
- 5) Reports shall be issued to VA Chief, Radiology Service, for corrective action and for filing.
- 6) Dosimeter Requirements
 - a) Specify personnel radiation monitoring dosimeter requirements
 - b) Review reports of personnel radiation doses
 - c) Investigate unusual exposures.
 - d) Maintain required dosimeter reports.
 - e) Advise on corrective action to prevent unnecessary exposures.
 - f) Assemble and maintain exposure history and provide to employees upon request, as required by law.
 - g) Advise Radiology management and the Clinical Radiation Safety Committee of methods of reducing exposures to staff and patients.
 - h) Design and evaluate new facilities for adequacy of shielding in accordance with standards established by the NCRP, the NHPP, and VAPAHCS and prepare a written report on the adequacy of the shielding.
 - i) Prepare evaluations of patient doses and associated risks of doses for clinical or research use involving exposure of patients and human subjects of machine-produced ionizing radiation in accordance with policies promulgated by the Clinical Radiation Safety Committee.

5.3 Special Contract Requirements

- 1) Services specified in this contract may be changed by written modification to the contract, prepared by VA Contracting Officer.
- 2) Other necessary personnel for the operation of the contractual services at VA will be provided by VA at mutually agreed-upon levels which are compatible with the safety of patients, personnel and quality-programmed medical care.

- 3) Services performed by the Contractor will be conducted under the direction of the Chief, Nuclear Medicine Service, Chief, Radiology Service, and ACOS for Research or their designees.
- 4) Qualifications. Personnel assigned by the Contractor to perform the services identified shall be appropriately licensed by the State, Territory or Commonwealth of the United States of America, District of Columbia, or by a national licensing organization in their field. Qualifications of such personnel shall also be subject to review by VAPAHCS Chief of Staff or approval by the Director, VAPAHCS.
- 5) The Contractor shall assume full responsibility for the protection of its personnel furnishing services under this contract. To carry out this responsibility, the Contractor shall provide the following:
 - a) Worker's compensation
 - b) Professional liability insurance
 - c) Health examinations
 - d) Social Security payments
 - e) Income tax withholding
- 6) Both parties agree that Contractor personnel shall not be considered VA employees for any purpose.

5.4 Monitoring Procedures

- 1) Contractor employees shall report, either in person or by telephone, to appropriate VA personnel in the area of service when coming to VA for inspection or service.
- 2) Stanford's Administrative Panel on Radiation Safety, Clinical Radiation Safety Committee, shall receive and review copies of all inspection reports submitted by Stanford.
- 3) Reports shall be submitted on a quarterly basis. Should any discrepancies or questions arise, Contractor will be notified immediately.

5.5 Contractor Experience Requirements

- 1) Personnel assigned by the Contractor to perform the services identified shall be appropriately licensed by a State, Territory or Commonwealth of the United States of America, District of Columbia or by a national licensing organization in their field.
- 2) Qualifications of such personnel shall also be subject to review by VAPAHCS Chief of Staff or approval by the Director, VAPAHCS.

5.6 Confidentiality and Nondisclosure

- 1) The contractor must agree to the following:
 - a) The preliminary and final deliverables, and all associated working papers, application source code, and other material deemed relevant by VA which have been generated by the contractor in the performance of this task order, are the exclusive property of the U.S. Government and shall be submitted to the Contracting Officer (CO) at the conclusion of the contract.
 - b) The CO will be the sole authorized official to release, verbally or in writing, any data, draft deliverables, final deliverables, or any other written or printed materials pertaining to this task order. No information shall be released by the contractor. Any request for information relating to this task order, presented to the contractor, shall be submitted to the CO for response.
 - c) Press releases, marketing material, or any other printed or electronic documentation related to this project, shall not be publicized without the written approval of the CO.

5.7 Contractor Personnel Security Requirements

- 1) All contractor employees who require access to the Department of Veterans Affairs' computer systems shall be the subject of a background investigation and must receive a favorable adjudication from the VA Office of Security and Law Enforcement prior to contract performance. This requirement is applicable to subcontractor personnel requiring the same access.

Section 6: Attachments

Attachment #1 - Security Requirements